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DEC 28 2007**REMARKS**

Applicants' undersigned attorney thanks the Examiner for her comments. Applicants respectfully request reconsideration of this patent application, particularly in view of the above Amendment and the following remarks. Currently, Claims 1-4 and 6-52 are pending, with Claims 2, 6-14, 16, 18, 19, 32, 33, and 47 withdrawn from consideration.

Amendment to the Claims

Claims 1, 3, 4, 15, 17, 20-31, 34-46, and 48-52 have been examined with no claims being allowed.

Claim 1 has been amended to include the limitation of the hinge mechanism being positioned on the main big toe joint. Support for this limitation is provided, for example, at page 7, line 16 – page 8, line 2; page 9, lines 27-30; and in Figures 1 and 1a.

Claim 28 has been amended to eliminate the term "tension element." Support for this amendment is provided, for example, at page 11, line 28 – page 12, line 12.

No new matter has been added by this Amendment. The total number of claims remains unchanged, and the number of independent claims also remains unchanged. Therefore, no additional claim fee is due.

Drawings

The "tension element," recited in Claim 28 has been canceled from the claim, thereby rendering the drawing objection moot.

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Claim Rejections - 35 U.S.C. §102

The rejection of Claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 under 35 U.S.C. §102(b) as anticipated by Wilms, U.S. Patent 1,213,786, is respectfully traversed.

Amended Claim 1 recites a flexible splint which is held by the fastening provisions in the regions of the big toe and the central foot and which extends along an inner side of the foot. The flexible splint is formed as a hinged flexible splint, articulated in a direction of flexion and extension of a toe or toes requiring correction, and includes a **hinge mechanism positioned on the main big toe joint and having a pivot axis that corresponds approximately to the joint axis of the main big toe joint in the direction of flexion and extension.**

With the pivot axis corresponding approximately to the joint axis of the main big toe joint, a force (F1) can be exerted on the big toe in the direction of the inner side of the foot by the flexible splint while a force (F2) is exerted on the main big toe joint region by the hinge mechanism in a direction *opposite* the force (F1). As further explained at page 7, line 29 – page 8, line 2 of Applicants' specification, a supporting force (F3) is exerted on the central foot in the *same direction as the force (F1)*, with the force (F3) being absorbed by the central foot. Arrows indicating the directions of these forces are illustrated in Figures 1 and 1a.

More particularly, the main big toe joint is the joint between the 1st metatarsal and the proximal phalange. By positioning the pivot axis of the hinge mechanism at this location and securing opposing ends of the flexible splint about the big toe and the central foot, *opposing forces* are exerted on the big toe and the pivot axis.

In contrast, the Wilms reference discloses a splint that is secured to the big toe at one end and to the central foot at the other end, with a **pivot axis positioned at the central foot end**. Consequently, the forces exerted by the splint at the big toe and at the pivot axis are acting upon the foot in the *same direction*.

Furthermore, Applicants' claimed device allows the wearer's big toe joint to bend, which provides greater comfort to a wearer. In contrast, the device disclosed in the Wilms reference inhibits bending at the big toe joint, with a rigid "joint receiving pocket 13" that is designed to merely be placed atop this joint. More particularly, as

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described at page 2, lines 23-38 of the Wilms reference, the device therein is designed to pivotally adjust the placement of the two metal members 10 and 25 in order to correctly place the front edge of the tongue 30 (on the bottom of the foot) with respect to the joint receiving pocket 13. Contrary to the Examiner's assertions, the rivet 16 is obviously offset from the joint axis of the main big toe joint, particularly since the joint receiving pocket 13 is intended to be aligned with the joint axis of the main big toe joint, and it is clear from both the text and the figures in the Wilms reference that the pivot axis of the rivet 16 is not intended to correspond approximately to the joint axis of the main big toe joint in the direction of flexion and extension.

Consequently, the pivot axes in Applicants' claimed invention and in the Wilms reference, due to their differing locations and the differing structures to which they are attached, function in completely different capacities.

For at least the reasons given above, Applicants respectfully submit that the teachings of Wilms fail to disclose Applicants' claimed invention. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Claim Rejections - 35 U.S.C. §103

A. Wilms

The rejection of Claims 48 and 50 under 35 U.S.C. §103(a) as being unpatentable over Wilms, U.S. Patent 1,213,786, is respectfully traversed. Claims 48 and 50 depend from amended Claim 1, and are thus patentable for at least the same reasons discussed above.

Furthermore, MPEP § 2143.01(V), E8r6, provides that "the proposed modification [of the prior art] cannot render the prior art unsatisfactory for its intended purpose." By relocating the pivot axis of the hinge mechanism in Wilms to be positioned over the main big toe joint, the device would not be able to pivotally adjust the placement of the two metal members 10 and 25 in order to correctly place the front edge of the tongue 30 (on the bottom of the foot) with respect to the joint receiving pocket 13 (i.e., over the joint) because the rivet 16 would be within the joint receiving pocket 13, thus defeating the purpose of Wilms.

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B. Wilms in view of Willner et al.

The rejection of Claim 25 under 35 U.S.C. §103(a) as being unpatentable over Wilms, U.S. Patent 1,213,786, as applied to Claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 above and further in view of Willner et al., U.S. Patent 5,897,515, is respectfully traversed, particularly in view of the following remarks.

Willner et al. fails to overcome the above-explained deficiencies of Wilms. More particularly, neither Wilms nor Willner et al. disclose or suggest a hinged flexible splint that includes a **hinge mechanism positioned on the main big toe joint and having a pivot axis that corresponds approximately to the joint axis of the main big toe joint** in the direction of flexion and extension. The substitution of the materials in the Willner et al. reference into the device of Wilms would fail to achieve Applicants' claimed invention.

For at least the reasons given above, Applicants respectfully submit that the teachings of Wilms in view of Willner et al. fail to disclose or suggest Applicants' claimed invention. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

C. Wilms in view of Scholl

The rejection of Claims 27 and 28 under 35 U.S.C. §103(a) as being unpatentable over Wilms, U.S. Patent 1,213,786, as applied to Claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 above and further in view of Scholl, U.S. Patent 1,055,810, is respectfully traversed.

Scholl fails to overcome the above-explained deficiencies of Wilms. More particularly, neither Wilms nor Scholl disclose or suggest a hinged flexible splint that includes a **hinge mechanism positioned on the main big toe joint and having a pivot axis that corresponds approximately to the joint axis of the main big toe joint** in the direction of flexion and extension. Furthermore, both prior art references teach rigid single-piece splints. Thus, there is no teaching, suggestion, or motivation in either of these references, alone or in combination, that would have led one of ordinary skill to modify or combine these references to arrive at Applicants' claimed invention.

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For at least the reasons given above, Applicants respectfully submit that the teachings of Wilms in view of Scholl fail to disclose or suggest Applicants' claimed invention. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

D. Wilms in view of Tyrrell

The rejection of Claims 22, 34-36, and 38-46 under 35 U.S.C. §103(a) as being unpatentable over Wilms, U.S. Patent 1,213,786 as applied to Claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 above and further in view of Tyrrell, U.S. Patent 6,254,559, is respectfully traversed.

Tyrrell fails to overcome the above-explained deficiencies of Wilms. More particularly, neither Wilms nor Tyrrell disclose or suggest a hinged flexible splint that includes a **hinge mechanism positioned on the main big toe joint and having a pivot axis that corresponds approximately to the joint axis of the main big toe joint** in the direction of flexion and extension. Despite the fact that Wilms and Tyrrell are both directed to orthopedic devices, there is no teaching, suggestion, or motivation in either of these references, alone or in combination, that would have led one of ordinary skill to modify or combine these references to arrive at Applicants' claimed invention. In particular, as explained above, relocating the pivot axis of the hinge mechanism in Wilms to be positioned over the main big toe joint would render the device in Wilms unsatisfactory for its intended purpose.

For at least the reasons given above, Applicants respectfully submit that the teachings of Wilms in view of Tyrrell fail to disclose or suggest Applicants' claimed invention. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

E. Wilms in view of Dondero

The rejection of Claim 52 under 35 U.S.C. §103(a) as being unpatentable over Wilms, U.S. Patent 1,213,786, as applied to Claims 1, 3, 4, 15, 17, 20, 21, 23, 24, 26, 29-31, 37, 49, and 51 above and further in view of Dondero, U.S. Patent 7,200,875, is respectfully traversed, particularly in view of the following remarks.

Dondero fails to overcome the above-explained deficiencies of Wilms. More particularly, neither Wilms nor Dondero disclose or suggest a hinged flexible splint

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that includes a **hinge mechanism positioned on the main big toe joint and having a pivot axis that corresponds approximately to the joint axis of the main big toe joint** in the direction of flexion and extension. There is no teaching, suggestion, or motivation in either of these references, alone or in combination, that would have led one of ordinary skill to modify or combine these references to arrive at Applicants' claimed invention.


For at least the reasons given above, Applicants respectfully submit that the teachings of Wilms in view of Dondero fail to disclose or suggest Applicants' claimed invention. Accordingly, reconsideration and withdrawal of this rejection is respectfully requested.

Conclusion

Applicants intend to be fully responsive to the outstanding Office Action. If the Examiner detects any issue which the Examiner believes Applicants have not addressed or resolved in this response, Applicants' undersigned attorney requests a telephone interview with the Examiner.

Applicants sincerely believe that this Patent Application is now in condition for allowance and, thus, respectfully request early allowance.

Respectfully submitted,


Melanie I. Rauch
Registration No. 40,924

Pauley Petersen & Erickson
2800 West Higgins Road
Suite 365
Hoffman Estates, Illinois 60169
(847) 490-1400
FAX (847) 490-1403